

CASE 33316A

FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10	
EY 971833452 Express Mail Label Number	11/14/07 Date of Deposit

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE PCT NATIONAL STAGE APPLICATION OF

Art Unit: 1614

DESSET-BRETHES ET AL.

INTERNATIONAL APPLICATION NO: PCT/EP04/013419

FILED: 25 NOVEMBER 2004

U.S. APPLICATION NO: 10/580,895

35 USC §371 DATE: MARCH 13, 2007

FOR: COMPOSITIONS COMPRISING ORGANIC COMPOUNDS

Mail Stop:PCT

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

LETTER TO CORRECT FILING RECEIPT AND U.S. PUBLICATION

Sir:

Applicants have now received the filing receipt in the above-identified application. However, in viewing the paper, Applicants noted that the "**Applicant(s)**" information was incorrect. Three inventors were omitted. Applicants enclose a copy of the executed Declaration that shows this to be true.

Please issue a corrected filing receipt have the Applicants area read:

-- **Applicant(s)** Sabine Desset-Brèthes, Prattein, SWITZERLAND;
Andreas Meyer, Neuenburg, GERMANY
Jörg Ogorka, Steinen, GERMANY;
Jean-Pierre Cassiere, Rueil Malmaison, FRANCE;
Armelle Decouz, Orléans, FRANCE; --.

A copy of the filing receipt with the correction noted is enclosed herewith.

No fee is believed to be required by this request for a corrected filing receipt.

Upon receipt of the **Notice of Publication of Application**, Applicants also noted that the same inventors were omitted on the **U.S. Publication No. 2007/0218134 A1**. A copy of the title page of the U.S. publication is enclosed herewith.

Please correct this error as soon as possible, to avoid problems in the future.

Respectfully submitted,

Novartis

Corporate Intellectual Property
One Health Plaza, Building 104
East Hanover, NJ 07936-1080
(862) 778-3096

Encls.: copy of filing receipt
copy of declaration
copy of the title page of instant publication

Date: Nov. 14, 2007


Cynthia H. Zhang
Attorney for Applicants
Reg. No. 53,827

DECLARATION AND POWER OF ATTORNEY FOR UNITED STATES PATENT APPLICATION

☒ Original

☐ Supplemental

☐ Substitute

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name, and

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if more than one name is listed below) of the subject matter which is claimed and for which a United States patent is sought on the invention entitled

COMPOSITIONS COMPRISING ORGANIC COMPOUNDS

the specification of which:

☐ is attached hereto.

☐ was filed on _____ as Application No. _____
(day/month/year)

and, if this box (☐) contains an *

☐ was amended on _____
(day/month/year)

☒ was filed as Patent Cooperation Treaty international Application No.

PCT/ EP2004/013419 on 25-11-2004
(day/month/year)

and, if this box (☐) contains an *

☐ entered the national stage in the United States and was accorded Application No. _____

and, if this box (☐) contains an *

☐ was amended, subsequent to entry into the national stage, on _____
(day/month/year)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment(s) specifically referred to above and, if this application was filed as a Patent Cooperation Treaty international application, by any amendments made during the international stage (including any made under Patent Cooperation Treaty Rule 91, Article 19 and Article 34).

I acknowledge my duty to disclose information which is material to patentability as defined in 37 C.F.R. 1.56, including, for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or Patent Cooperation Treaty international filing date of the continuation-in-part application.

I hereby claim the benefit under 35 U.S.C. 119(a)-(d) or (f) or 365(b) of any foreign application(s) for patent, inventor's certificate or plant breeder's right certificate listed below and under 35 U.S.C. 365(a) of any Patent Cooperation Treaty international application(s) designating at least one country other than the United States listed below and have also listed below any foreign application(s) for patent, inventor's certificate or plant breeder's right certificate and Patent Cooperation Treaty international application(s) designating at least one country other than the United States for the same subject matter and having a filing date before that of the application the priority of which is claimed for that subject matter:

COUNTRY/REGION (OR P.C.T.)	APPLICATION No.	FILING DATE (day/month/year)	PRIORITY CLAIMED
-------------------------------	-----------------	---------------------------------	------------------

☐ Yes ☐ No
☐ Yes ☐ No
☐ Yes ☐ No
☐ Yes ☐ No
☐ Yes ☐ No

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below:

APPLICATION NO.	FILING DATE (day/month/year)
-----------------	---------------------------------

60/525373

26-11-2003

I hereby claim the benefit under 35 U.S.C. 120 of any United States application(s) listed below and under 35 U.S.C. 365(c) of any Patent Cooperation Treaty international application(s) designating the United States listed below:

United States Application No.	United States Filing Date (day/month/year)	Status (Pending, Abandoned or U.S. Patent No.)	International Application No. and Filing Date (day/month/year)
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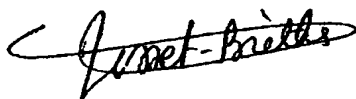
I hereby appoint all of the registered practitioners associated with Customer No. 001095, respectively and individually, as my attorneys and agents, with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

If this box (☐) contains an x ☒, I hereby authorize the registered practitioners associated with Customer No. 001095 and any others acting on my behalf to take any action relating to this application based on communications from Corporate Intellectual Property of Novartis International AG, Basle, Switzerland, or an affiliate thereof or a successor thereto, without direct communication from me.

Please send all correspondence relating to this application to the address associated with Customer No. 001095.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Full name of sole or first joint inventor	Sabine DESSET-BRÉTHES	
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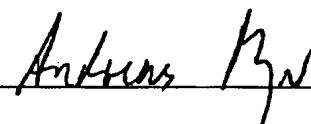
Inventor's signature		Date <u>16.05.06</u> (day/month/year)
----------------------	---	--

Residence	4133 Pratteln, Switzerland
-----------	-----------------------------------

Citizenship	citizen of France
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Post Office Address	Hauptstrasse 46B 4133 Pratteln Switzerland
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Full name of second joint inventor, if any	Andreas MEYER	
--	----------------------	--

Inventor's signature		Date <u>16.05.2006</u> (day/month/year)
----------------------	---	--

Residence	79395 Neuenburg, Germany
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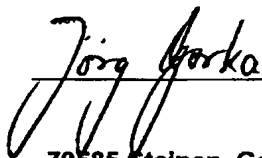
Citizenship	citizen of Germany
-------------	---------------------------

Post Office Address	Akazienweg 1 79395 Neuenburg Germany
---------------------	---

Full name of third
joint inventor, if any

Jörg OGORKA

Inventor's signature



Date

17/05/06
(day/month/year)

Residence

79585 Steinen, Germany

Citizenship

citizen of Germany

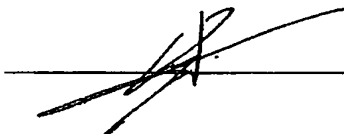
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Im Steinbrunnen 19/3
79585 Steinen
Germany

Full name of fourth
joint inventor, if any

Jean-Pierre CASSIERE

Inventor's signature



Date

29/05/06
(day/month/year)

Residence

92500 Rueil Malmaison, France

Citizenship

citizen of France

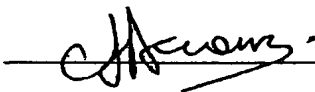
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Full name of fifth
joint inventor, if any

Armelle DECOUZ

Inventor's signature



Date

13 June 06.
(day/month/year)

Residence

45000 Orléans, France

Citizenship

citizen of France

Post Office Address

6 rue des tanneurs
45000 Orléans
France

US Case 33316-US-PCT

IMPORTANT: Before this declaration is signed, the patent application (the specification, the claims and this declaration) must be read and understood by each person signing it, and no changes may be made in the application after this declaration has been signed.

MWM



UNITED STATES PATENT AND TRADEMARK OFFICE

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APPL NO.	FILING OR 371(c) DATE	ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	TOT CLMS	IND CLMS
10/580,895	03/13/2007	1614	1030	33316A	19	1

CONFIRMATION NO. 9283

1095
 NOVARTIS
 CORPORATE INTELLECTUAL PROPERTY
 ONE HEALTH PLAZA 104/3
 EAST HANOVER, NJ 07936-1080

FILING RECEIPT



OC000000024345799

Date Mailed: 06/14/2007

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please mail to the Commissioner for Patents P.O. Box 1450 Alexandria Va 22313-1450. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s)

Sabine Desset-Brethes, Prattein, SWITZERLAND;
 Andreas Meyer, Neuenburg, GERMANY;

*omitted 3 inventors
 (see letter) Declaration*

Power of Attorney: The patent practitioners associated with Customer Number 001095.

Domestic Priority data as claimed by applicant

This application is a 371 of PCT/EP04/13419 11/25/2004
 which claims benefit of 60/525,373 11/26/2003



Foreign Applications

If Required, Foreign Filing License Granted: 06/13/2007

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US10/580,895**

Projected Publication Date: 09/20/2007

Non-Publication Request: No

Early Publication Request: No

Title

Compositions Comprising Organic Compounds

Preliminary Class

514

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

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Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

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Title 35, United States Code, Section 184
Title 37, Code of Federal Regulations, 5.11 & 5.15**

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US 20070218134A1

(19) **United States**(12) **Patent Application Publication****Desset-Brethes et al.**(10) **Pub. No.: US 2007/0218134 A1**(43) **Pub. Date: Sep. 20, 2007**(54) **COMPOSITIONS COMPRISING ORGANIC COMPOUNDS**(76) Inventors: **Sabine Desset-Brethes**, Prattein (CH);
Andreas Meyer, Neuenburg (DE)

Correspondence Address:

NOVARTIS**CORPORATE INTELLECTUAL PROPERTY****ONE HEALTH PLAZA 104/3****EAST HANOVER, NJ 07936-1080 (US)**(21) Appl. No.: **10/580,895**(22) PCT Filed: **Nov. 25, 2004**(86) PCT No.: **PCT/EP04/13419**

§ 371(c)(1),

(2), (4) Date: **Mar. 13, 2007****Related U.S. Application Data**

(60) Provisional application No. 60/525,373, filed on Nov. 26, 2003.

Publication Classification(51) **Int. Cl.****A61K 9/22** (2006.01)(52) **U.S. Cl.** **424/471**(57) **ABSTRACT**

The present invention relates to pharmaceutical compositions for sustained release comprising as active ingredient an HMG-CoA reductase inhibitor or a pharmaceutically acceptable salt thereof, said composition comprising a core consisting of an inner phase (internal) and an outer phase (external) wherein the outer phase does not comprise a matrix former and wherein the core is first coated with a non functional film coat and then with an enteric coat.